

109TH CONGRESS
2D SESSION

S. 2699

To promote the research and development of drugs related to neglected
and tropical diseases, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 2, 2006

Mr. BROWNBACK (for himself and Mr. LIEBERMAN) introduced the following
bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To promote the research and development of drugs related
to neglected and tropical diseases, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Elimination of Ne-
5 glected Diseases Act of 2006”.

6 **SEC. 2. PATENT EXTENSION AND RESTORATION.**

7 (a) IN GENERAL.—Chapter 14 of title 35, United
8 States Code, is amended by inserting after section 156 the
9 following:

1 **“§ 156a. Extension and restoration of patent terms re-**
2 **lating to neglected and tropical diseases**

3 “(a) DEFINITIONS.—In this section, the term—

4 “(1) ‘AIDS’ means the acquired immune defi-
5 ciency syndrome;

6 “(2) ‘AIDS drug’ means a drug indicated for
7 treating HIV;

8 “(3) ‘eligible patent’ means a patent that—

9 “(A) claims—

10 “(i) an approved new molecular entity
11 standard review drug;

12 “(ii) an active ingredient of such new
13 molecular entity standard review drug;

14 “(iii) a process of making or using the
15 new molecular entity standard review drug;

16 or

17 “(iv) a process of making an active in-
18 gredient of such new molecular entity
19 standard review drug; and

20 “(B) is owned by or licensed to a person
21 that has filed and received approval of an appli-
22 cation described in section 505(b)(1) of the
23 Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 355(b)(1)), for a tropical disease prod-
25 uct;

1 “(4) ‘HIV’ means the human immunodeficiency
2 virus, the pathogen that causes AIDS;

3 “(5) ‘neglected or tropical disease’ means—

4 “(A) HIV, malaria, tuberculosis, and re-
5 lated diseases; or

6 “(B) any other infectious disease that dis-
7 proportionately affects poor and marginalized
8 populations, including those diseases targeted
9 by the Special Programme for Research and
10 Training in Tropical Diseases cosponsored by
11 the United Nations Development Program,
12 UNICEF, the World Bank, and the World
13 Health Organization;

14 “(6) ‘new molecular entity standard review
15 drug’—

16 “(A) means a drug that—

17 “(i) has never been marketed in the
18 United States;

19 “(ii) appears to have therapeutic
20 qualities superior to the therapeutic quali-
21 ties of another drug that is marketed in
22 the United States; and

23 “(iii) is designated by the Secretary of
24 Health and Human Services under section
25 524 of the Federal Food, Drug, and Cos-

1 metetic Act as having a new molecular entity
2 chemical type classification and standard
3 review drug treatment potential classifica-
4 tion, other than drugs developed to treat
5 serious or life-threatening diseases; and

6 “(B) shall not include a subpart E drug or
7 an AIDS drug;

8 “(7) ‘regulatory review period’ means the period
9 described under section 506(g)(1)(B);

10 “(8) ‘subpart E drug’ means a drug developed
11 or evaluated under special procedures for drugs to
12 treat life-threatening or severely debilitating illnesses
13 under subpart E of part 312 of title 21 of the Code
14 of Federal Regulations; and

15 “(9) ‘tropical disease product’ means a product
16 that—

17 “(A) is approved for use in the treatment
18 of a neglected or tropical disease;

19 “(B) is a new drug, antibiotic drug, bio-
20 logical product, device, diagnostic, or other tool
21 for treatment, as those terms are used in the
22 Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 301 et seq.) and the Public Health Serv-
24 ice Act (42 U.S.C. 201 et seq.); and

1 “(C) is certified by the Secretary of Health
2 and Human Services under section 524 of the
3 Federal Food, Drug, and Cosmetic Act .

4 “(b) PATENT TERM EXTENSION.—The term of an el-
5 igible patent shall be extended by a period not to exceed
6 2 years and not less than 6 months in duration if—

7 “(1) an application in conformance with the re-
8 quirements of subsection (d) is submitted to the Di-
9 rector by either the owner of record of the patent or
10 its agent on the later of—

11 “(A) on or before the date specified under
12 subsection (d)(3); or

13 “(B) within 45 days after the date of
14 issuance of the patent;

15 “(2) the term of the eligible patent that is the
16 basis of the application has not expired prior to the
17 date that the application is submitted under sub-
18 section (d);

19 “(3) the regulatory review period for the trop-
20 ical disease product has not been relied upon to sup-
21 port an application to extend the term of another
22 patent under this section or under any other provi-
23 sion of law; and

1 “(4) the Food and Drug Administration has
2 certified the eligibility of that tropical disease prod-
3 uct for patent extension.

4 “(c) PATENT TERM RESTORATION.—The term of a
5 patent for a tropical disease product shall be restored by
6 a period equal to the number of days in the regulatory
7 review period, if, with respect to the patent that is the
8 basis for application—

9 “(1) the owner of record of the patent or its
10 agent submits an application to the Director on the
11 later of—

12 “(A) on or before the date specified under
13 subsection (d)(3); or

14 “(B) on or before 45 days after the date
15 of issuance of the patent;

16 “(2) the patent has not been previously restored
17 or extended under this section;

18 “(3) the term of the patent has not expired
19 prior to the date that the owner of the record of the
20 patent or its agent submits an application to the Di-
21 rector;

22 “(4) the regulatory review period for the prod-
23 uct has not been relied upon to support an applica-
24 tion to extend the term of another patent under any
25 section of this title; and

1 “(5) the Food and Drug Administration has
2 certified the eligibility of that tropical disease prod-
3 uct for patent restoration.

4 “(d) ADMINISTRATIVE PROVISIONS.—

5 “(1) IN GENERAL.—To obtain an extension or
6 restoration of the term of an eligible patent or pat-
7 ent of a tropical disease product under this section,
8 the assigner of record and licensee of record of the
9 eligible patent or tropical disease product or the
10 agent of the assigner of record and licensee shall
11 submit an application to the Director.

12 “(2) CONTENT.—The application shall con-
13 tain—

14 “(A) a description of the approved tropical
15 disease product and the Federal statute under
16 which regulatory review relating to such prod-
17 uct occurred;

18 “(B) the identity of—

19 “(i) the eligible patent for which an
20 extension is sought under this section; or

21 “(ii) the patent for a tropical disease
22 product for which a restoration is sought
23 under this section;

24 “(C) an undertaking by the applicant to
25 make publicly available independently audited

1 financial statements to verify commercialization
2 of the approved tropical disease product; and

3 “(D) such other information as the Direc-
4 tor may require including additional informa-
5 tion to establish that the eligible patent or trop-
6 ical disease product meets the requirements of
7 this section.

8 “(3) SUBMISSION OF APPLICATION.—Upon sub-
9 mission of the application for approval of the trop-
10 ical disease product to the Food and Drug Adminis-
11 tration, the sponsor shall give notice of which patent
12 it would extend if the patent becomes eligible for the
13 extension or restoration upon successfully completing
14 the research. The Secretary of Health and Human
15 Services shall publish the notice.

16 “(4) IRREVOCABLE ELECTION.—The submis-
17 sion of an application under this section is an irrev-
18 ocable election of the application of this section to
19 the eligible patent or patent for a tropical disease
20 product that is the basis of the application. An eligi-
21 ble patent or patent for a tropical disease product
22 that is the basis of an application submitted under
23 this section may not be the subject of an application
24 made under section 156 or any other provision of
25 law.

1 “(5) RULE OF CONSTRUCTION.—Nothing in
 2 this section shall be construed to prohibit an exten-
 3 sion, under an application made under any other
 4 section of this title, of the term of a patent relating
 5 to a tropical disease product that, prior to the effec-
 6 tive date of this section, was approved for commer-
 7 cial marketing for a nontropical disease use.

8 “(e) LIMITATION.—An eligible patent may not be ex-
 9 tended under this section if—

10 “(1) the tropical disease product was approved
 11 for commercial marketing prior to the date of enact-
 12 ment of this section; or

13 “(2) the eligible patent that is the basis of the
 14 application under this section expired prior to the
 15 date of enactment of this section.”.

16 (b) DESIGNATION FOR PATENT EXTENSION AND
 17 RESTORATION.—Chapter V of the Federal Food, Drug,
 18 and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by
 19 inserting after section 523 the following:

20 **“SEC. 524. DESIGNATION FOR PATENT EXTENSION AND**
 21 **RESTORATION.**

22 “(a) DEFINITIONS.—In this section:

23 “(1) NEW MOLECULAR ENTITY STANDARD RE-
 24 VIEW DRUG.—The term ‘new molecular entity stand-

1 ard review drug’ has the meaning given that term in
2 section 156a of title 35, United States Code.

3 “(2) TROPICAL DISEASE PRODUCT.—The term
4 ‘tropical disease product’ has the meaning given that
5 term in section 156a of title 35, United States Code.

6 “(b) NEW MOLECULAR ENTITY STANDARD REVIEW
7 DRUG.—The Secretary, acting through the Commissioner
8 of Food and Drugs—

9 “(1) shall designate a drug as a new molecular
10 entity standard review drug for purposes of section
11 156a of title 35, United States Code, if that drug—

12 “(A) has a new molecular entity chemical
13 type classification and standard review drug
14 treatment potential classification; and

15 “(B) is not a drug developed to treat seri-
16 ous or life-threatening diseases;

17 “(2) shall apply the guidance issued in calendar
18 year 2002 on serious or life-threatening diseases for
19 purposes of paragraph (1)(B);

20 “(3) shall maintain and annually update a clas-
21 sification list of serious and life-threatening diseases;
22 and

23 “(4) may remove the designation of a drug as
24 a new molecular entity standard review drug as des-
25 ignated under paragraph (1).

1 “(c) TROPICAL DISEASE PRODUCTS.—The Secretary
 2 shall certify tropical disease products for purposes of sec-
 3 tion 156a of title 35, United States Code.”.

4 (c) TECHNICAL AND CONFORMING AMENDMENT.—
 5 The table of sections for chapter 14 of title 35, United
 6 States Code, is amended by inserting after the item relat-
 7 ing to section 156 the following:

“156a. Extension and restoration of patent terms relating to neglected and trop-
 ical diseases.”.

8 (d) STUDY AND REPORT.—

9 (1) STUDY.—The Director of the United States
 10 Patent and Trademark Office, in conjunction with
 11 the Food and Drug Administration, the Department
 12 of Health and Human Services, and the United
 13 States Agency for International Development, shall
 14 conduct a study on the effect of patent extension
 15 and restoration on the ability of pharmaceutical
 16 companies to develop and distribute tropical disease
 17 products for poor and marginalized populations.

18 (2) REPORT.—Not later than 1 year after the
 19 date of the enactment of this Act, the Director of
 20 the United States Patent and Trademark Office
 21 shall submit a report on the results of the study
 22 under paragraph (1) to—

1 (A) the Committee on Foreign Relations of
2 the Senate and the Committee on Health, Edu-
3 cation, Labor, and Pensions of the Senate; and

4 (B) the appropriate committees of the
5 House of Representatives.

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